EXHIBIT 80

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 331-4902

July 21, 2008

Anthony Delicato
Director Quality Assurance
Actavis Elizabeth LLC
200 Elmora Avenue
Elizabeth, New Jersey 07202

Dear Mr. Delicato:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection conducted of your facility located at the above address on May 21, 2008 by Douglas Kovacs on behalf of the U.S. Food and Drug Administration (FDA). This report is being provided to you for information purposes. This new procedure is applicable to EIRs for inspections completed on or after April 1, 1997. For those inspections completed prior to the above date, a copy of the EIR may still be made available through the Freedom of Information Act (FOIA).

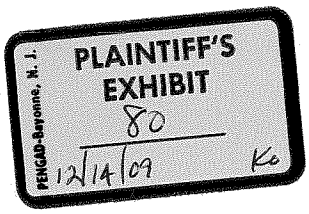
The Agency is working to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it reflects redactions made by the Agency in accordance with the FOIA and 21 CFR Part 20. This, however, does not preclude you from requesting and, possibly, obtaining any additional information under FOIA.

If there is any question about the released information, feel free to, contact Nancy Rolli, Compliance Branch Director, at the number or address listed above.

Very truly yours,

Sarah A. DellaFave
Compliance Officer
New Jersey District Office

SAD:slm



Establishment Inspection Report	FEI:	**2211563**
Actavis Elizabeth LLC	EI Start:	04/21/2008
Elizabeth, NJ 07202-1106	EI End:	05/21/2008

RELEASED TO INSP. FIRM

7/22/08
DATE NWJ-DO

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SUMMARY

Inspection of this generic pharmaceutical manufacturer was initiated as FACTS Assignment [redacted] follow-up to warning letter 06-NWJ-15 issued to the firm's Little Falls, New Jersey location for PADE reporting was conducted. Inspectional guidance was provided through CP 73.56002, Drug Manufacturing Inspections, CP 7346.832, Pre-approval Inspections/Investigations and CP 7353.001, Enforcement of the Postmarketing Adverse Drug Experience Reporting Regulations.

The previous inspection of 2/21/2008 and 4/3/2008 covered Fentanyl Transdermal complaints and was classified VAI. The previous GMP inspection of 12/13/2006-1/29/2007 covered the Quality, Production, Laboratory Control and Materials Systems and was classified VAI. A GMP deficiency was noted that laboratory out-of-specifications results were not thoroughly investigated and were inconclusively attributed to analyst error. The previous PADE inspection of 8/11-14/2003 was classified NAI; however, the PADE inspection at the firm's Little Falls, New Jersey location from 1/10/2006 to 2/8/2006 revealed several deficiencies that included potential 15-day cases were not submitted to FDA; serious and unexpected ADE reports were not promptly or adequately investigated; cases were not reviewed for seriousness and expectedness; and there was a lack of written procedures. The inspection was classified OAI and a warning letter was issued for these deficiencies.

The current inspection covered the Quality, Production, Laboratory Control and Equipment and [redacted] reported to FDA, 15-day and periodic reports were submitted late to FDA and the granulation of Diclofenac Extended Release tablets was transported through a common manufacturing corridor without tray covers. The firm's management promised corrections. On 5/23/2008, approval recommendations were forwarded to the New Jersey Pre-approval Manager for ANDAs 77-513 and 40-283/S008.

On 5/21/2008, Form FDA 483, Inspectional Observations was issued to Anthony Delicato, Director, Quality Assurance, New Jersey Solid Oral Dosage, who promised corrective actions. Mr. Delicato indicated that a written response would be sent to the New Jersey District within 30 days. No samples were collected and no refusals were encountered.

ADMINISTRATIVE DATA

Inspected firm:	Actavis Elizabeth LLC
Location:	200 Elmora Ave Elizabeth, NJ 07202-1106
Phone:	908-527-9100
FAX:	
Mailing address:	200 Elmora Ave Elizabeth, NJ 07202-1106
Dates of inspection:	4/21/2008, 4/22/2008, 4/23/2008, 4/24/2008, 4/25/2008, 4/28/2008, 4/29/2008, 4/30/2008, 5/1/2008, 5/5/2008, 5/6/2008, 5/19/2008, 5/21/2008
Days in the facility:	13
Participants:	Douglas C. Kovacs, Investigator

On 4/21/2008, I displayed my credentials and issued Form FDA 482, Notice of Inspection to Anthony Delicato, Director Quality Assurance, who stated that he was the most responsible person at the facility. I explained the purpose of the inspection to Mr. Delicato.

On 5/19/2008, I displayed my credentials and issued a second Form FDA 482, Notice of Inspection to Anthony Delicato, Director Quality Assurance New Jersey, Solid Oral Dosage due to the break in the inspection from 5/6/2008 to 5/19/2008. It should be noted that Mr. Delicato's title had changed on 5/17/2008.

On 5/21/2008, I issued Form FDA 483, Inspectional Observations to Mr. Delicato, who promised corrections and stated that a written response would be sent to the New Jersey District Office within thirty days. The following people were also present at the closeout meeting:

- Sarita Thapar, Pharm.D., Director US Medical Affairs
- Christopher Young, Director, US Solid Oral Dose Operations
- Garret Wolan, Manager, Compliance

Post inspectional correspondence should be addressed to:
Anthony Delicato
Director, Quality Assurance, New Jersey, Solid Oral Dosage
Actavis Elizabeth LLC
200 Elmora Ave
Elizabeth, NJ 07202

HISTORY

[redacted]

responsible person at this site. Robert Wessman, CEO is the firm's most responsible person and maintains his office in Hafnarfijordur, Iceland. Organizational charts are included as **Exhibit 1.** The firm's US headquarters are located in Morristown, New Jersey. Management changes since the previous inspection include the addition of Phyllis Lambridis, Vice President, US Quality and Compliance and John Hetcher, Operations Controller-Elizabeth, and the departure of Nasrat Hakim, Vice President, Quality and Compliance; Samir Ghodbane, Vice President, R&D and Technical Services; and Donna Cordasco, Director, Quality Control and Process Improvements. For a complete list of personnel changes, refer to **Exhibit 2.** Operations occur Monday through Friday, twenty four hours per day and office hours are 8:30am to 5:00pm. There are 507 people at this site. Additional manufacturing sites are located in Little Falls and Totowa New Jersey; Lincolnton, North Carolina; and Baltimore, Maryland.

JURISDICTION/INTERSTATE COMMERCE

[redacted]

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

The following key people were present during the inspection:

- **Anthony Delicato, Director, Quality Assurance, New Jersey Solid Oral Dosage** facilitated the inspection and provided information with regard to investigations, change control, consumer complaints, process deviations, rejected batches, annual product reviews, process validations studies, and cleaning validation. During the inspection, Mr. Delicato's responsibilities extended to the Actavis New Jersey sites in Totowa and Little Falls, New

Jersey. Mr. Delicato reports to Phyllis Lambridis, Vice President, US Quality and Compliance.

- **Sarita Thapar, Pharm.D., Director, US Medical Affairs** provided information with regard to the firm's adverse drug experience reporting operations. She reports to Jasmine Shah, R.Ph., Vice President, US Regulatory Affairs.
- **Christopher Young, Director, US Solid Oral Dose Operations** was present for the closeout meeting on 5/21/2008. Mr. Young reports to Steinthor Palsson, Executive Vice President, Operations, US
- **Scott Allen, Director, Quality Control** provided information with regard to the laboratory operations. Mr. Allen reports to Phyllis Lambridis, Vice President, US Quality and Compliance.
- **Garret Wolan, Manager, Compliance** was present throughout the inspection. Mr. Wolan scribed each day and processed document requests. Mr. Wolan reports to Wanda Eng, Senior Director, Compliance.

Exhibit 4 is a complete list of personnel that participated in the inspection.

MANUFACTURING OPERATIONS

The firm continues to manufacture prompt and extended release tablets, and prompt, modified and extended release capsules. During the inspection, I reviewed manufacturing and laboratory investigations, change control documentation, annual product reviews, rejected batches, Field Alert reports, consumer complaints, process validation studies for Alprazolam ER Tablets and Propranolol Hydrochloride ER Capsules, manufacturing and laboratory equipment qualification studies, analytical method transfer studies, batch records, clean/use logs, cleaning validation studies, supplier qualification studies and written procedures.

A deficiency in manufacturing was noted in the handling of the granulation for Diclofenac ER Tablets **(refer to FDA 483 Observation 4).**

Pre-approval Coverage

[redacted]

[redacted]

Active Pharmaceutical Ingredients from Foreign Sources

The following table represents APIs rejected/returned from foreign sources between 5/1/06 and 5/4/2008

[redacted]

The lot number and reason for rejection for each API is listed in **Exhibit 8.**

POSTMARKETING ADVERSE DRUG EXPERIENCES

Operations

The Elizabeth, New Jersey site is responsible for reporting domestic and international adverse drug experience (ADE) information to FDA. The site processes approximately 100 cases a month. The Medical Affairs group relocated to Elizabeth, New Jersey from Piscataway, New Jersey in 5/2006. There are nine people employed in the Medical Affairs department, which include the Vice President, Regulatory US Affairs, Director US Medical Affairs, five Drug Safety Associates and 2 Medical Affairs Coordinators **(Exhibit 1; page 5).** Changes to the Medical Affairs department since 8/2003 are included in **Exhibit 9. Exhibits 10-12** are lists of products that Elizabeth, New Jersey has reporting responsibilities for. **Exhibit 13** is a list of products in which adverse drug information

is reported by third party. The firm uses Oracle AERS for processing and tracking reports. My review of operations included, but was not limited to 15-day reports, late reporting, periodic reports, deactivated cases, medical inquiries, lack of effect complaints and written procedures.

Actavis Totowa LLC Warning Letter Follow-up

In 8/2006, Actavis Totowa LLC, Little Falls, New Jersey received a warning letter for their PADE reporting system. Deficiencies cited on the warning letter included:

- Potential 15-day cases were not submitted to FDA
- Serious and unexpected ADE reports were not promptly or adequately investigated
- Cases were not reviewed for seriousness and expectedness; submitted cases were classified as a 15-day report
- Periodic safety reports have never been submitted to FDA
- Written procedures have not been established for follow-up investigations, adequate completion of MedWatch forms, maintenance of records to assure timely submission of 15-day reports and evaluation of adverse event data for serious outcome and event expectedness.

Corrective actions to the warning letter included transferring reporting responsibilities for products manufactured in Little Falls to Actavis Elizabeth. According to Sarita Thapar, Pharm.D., Director, US Medical Affairs, the products were merged into their operations and did not require additional procedures. My review of the firm's operations included the issues cited in the warning letter. A similar deficiency that I observed during the inspection included unreported ADE information **(refer to FDA 483 Observation 1).**

Waivers

According to Dr. Thapar, the firm has waivers **(Exhibit 14)** with the FDA for non-serious labeled events and a realignment of dates for review of periodic reports.

Global Sites

The firm has sites throughout the world for collecting ADE information **(Exhibit 15).** The collected information is then forwarded to the Denmark site. If the adverse drug experience is associated with a drug product that has the same chemical moiety that is marketed in the US, then the information is forwarded to Elizabeth, New Jersey for evaluation, processing and submission to FDA. Dr. Thapar informed me that the Denmark site was responsible for obtaining follow-up information for the non-US sourced reports. Other responsibilities of the Denmark site are included in **Exhibit 16.** Dr. Thapar provided the firm's written procedures for the exchange of cases with their international affiliates **(Exhibit 17).** During the inspection, I noted that prior to 3/1/2006, ADE information was not forwarded to the firm's US site for evaluation and submission if the cases met the criteria of serious and unlabeled **(refer to Observation 1).**

Literature Searches

Literature searches are performed weekly by the firm's site in Denmark. The firm uses "Reactions Weekly" for their searches. 15-day reports are subsequently submitted by the Elizabeth, New Jersey site.

Safety Agreements

The firm maintains safety agreements with third party contractors. I requested and reviewed agreements with Prosar, St Paul, Minnesota, who reports ADE information to the FDA for Fentanyl Transdermal Patches and Mylan, who receives ADE information for Digitek Tablets and forwards the information to Actavis Elizabeth for processing and submission to FDA. I did not observe any deficiencies.

Patient Assistance/Physician Samples

The firm does not participate in any patient assistance programs nor do they distribute physician samples for any of their products.

Deactivated Cases

The firm deactivates cases from the Oracle AERS database if the case is a duplicate or a literature case that does not meet the criteria for submission. I reviewed several deactivated cases with Dr. Thapar and observed that each case included a reason for deactivation. In request of the written procedures for deactivating cases, Dr. Thapar indicated that they did not have a formal SOP; however, she provided a memo describing how the cases would be deactivated **(Exhibit 18)**. I discussed with Dr. Thapar and Mr. Delicato that the procedures for deactivating cases should be formalized. During the inspection, Mr. Delicato provided a revision to SOP MA-002, Management of Suspected Adverse Drug Reaction Reports, which included deactivating cases **(Exhibit 19)**.

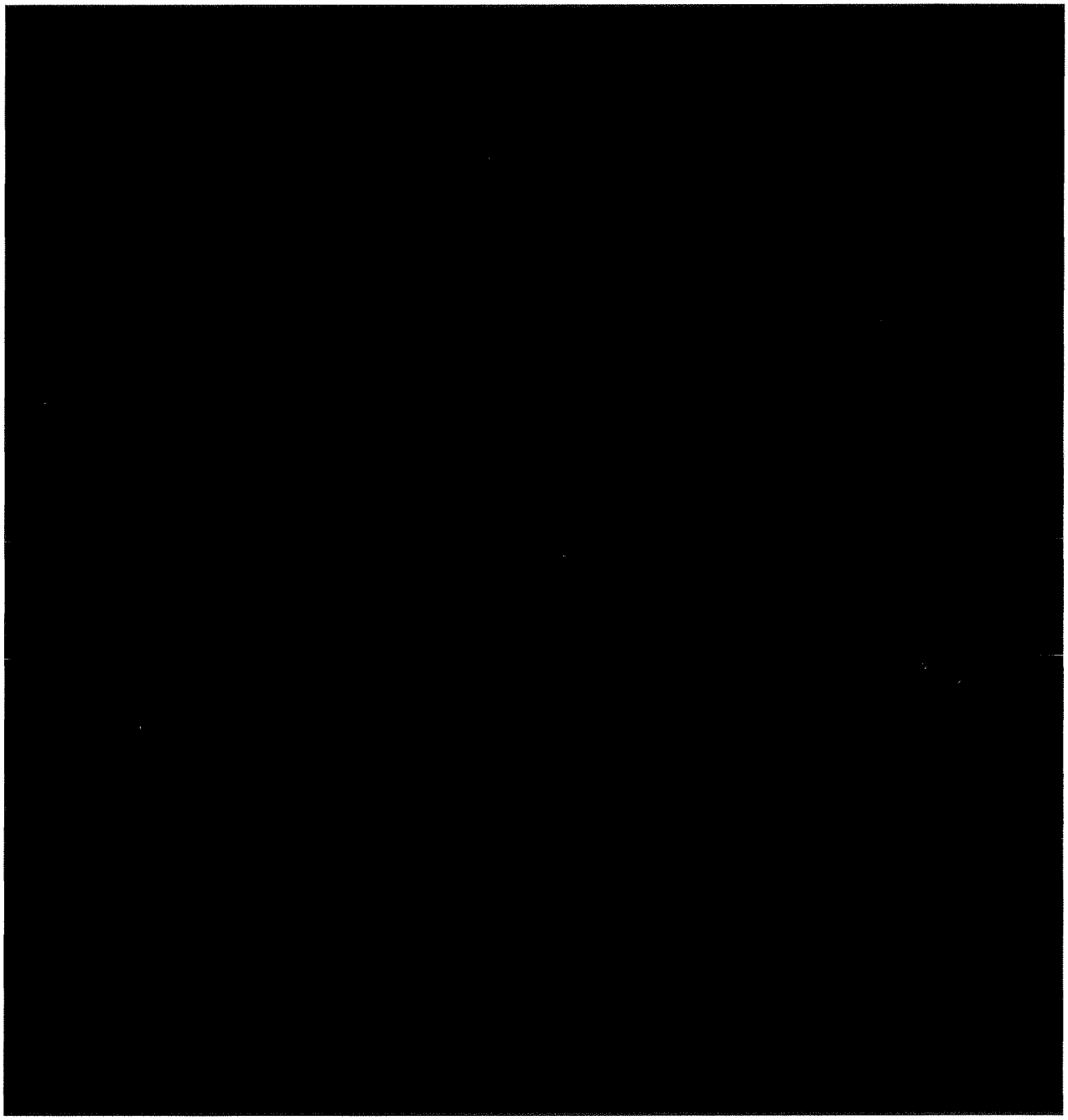
OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

On 5/21/2008, I issued Form FDA 483, Inspectional Observations to Anthony Delicato, Director, Quality Assurance, New Jersey, Solid Oral Dosage. Mr. Delicato indicated that a written response would be submitted to the New Jersey District within thirty days.

Observations listed on form FDA 483

Postmarketing Adverse Drug Experiences

[redacted]



At the closeout meeting, Mr. Delicato stated that the unreported cases from January and February 2006 would be submitted to FDA; however, Mr. Delicato informed me that they did not have a definitive answer to how far back they would go in reviewing unreported cases. He stated that they would include this information in their written response to the New Jersey District.

OBSERVATION 2

Not all adverse drug experiences that are both serious and unexpected have been reported to FDA within 15 calendar days of initial receipt of the information.

a. Specifically, between July 2006 and August 2006, the firm's Denmark site forwarded approximately 200 serious and unlabeled adverse drug event cases late to the firm's Elizabeth, New Jersey site for processing and submission to FDA. Although the adverse drug experience information was collected by the Denmark site, the date received as reported on the MedWatch form was the date received by the Elizabeth, New Jersey facility. Examples include:

[redacted]

b. Additionally, at least thirty (30) 15-day reports were submitted late to FDA between 4/2006 and 4/2008. Examples include:

[redacted]

ii. Case 2008AL001710, Digoxin Tablets, received on 2/7/2008 and submitted to FDA on 3/31/2008.
iii. Case 2008AL001222, Amlodipine Besylate Tablets, received on 1/11/2008 and submitted to FDA on 3/7/2008.
iv. Case 2008AL001104, Temazepam Capsules, received on 1/17/2008 and submitted to FDA on 3/7/2008.
v. Case 2008AL000910, Tramadol Hydrochloride Tablets, received on 1/7/2008 and submitted to FDA on 2/21/2008.

Reference: 21 CFR 314.80(c)(1)(i)

Discussion with Management:

During my review of serious and unlabeled adverse drug event cases, I noted a 15-day report, case 2006AL001965 **(Exhibit 27)** with an incorrect "Date received by manufacturer" on the MedWatch Form in comparison with the source data **(Exhibit 27; page 10).** The case was received at the Denmark site on 4/4/2006, forwarded to Actavis Elizabeth on 7/24/2006 and submitted to FDA on 8/8/2006. Dr. Thapar discussed with me that from March 2006 to August 2006, Actavis in Denmark sent approximately 200 cases to Actavis Elizabeth for processing and submission to FDA. Dr. Thapar explained that although the agreement for exchange began on 3/1/2006, the Denmark facility collected the cases starting on that date and began sending them to Actavis Elizabeth on 7/24/2006. For these cases, the Actavis Elizabeth started day 0 when they received the reports. A memo, dated 8/31/2006 was included in the case file for 2006AL001965 and documented the firm's decision to begin day 0 when the ADE information was received as Actavis Elizabeth for these cases **(Exhibit 27; page 2).** The memo also indicated that beginning on 9/15/2006, day 0 would begin when the ADE information is received at the firm's Denmark site.

I discussed the importance of providing accurate information, such as the date received, with the MedWatch. Dr. Thapar agreed and informed me that since 9/15/2006, the date received at the firm's Denmark site for non-US sourced cases were reported on the MedWatch form.

During the inspection, I also noted that the firm has submitted several (over 30) 15-day reports late to FDA over the past two years, excluding the non-US sourced case with the incorrect received date.

Approximately 1,330 15-day reports have been processed and submitted to FDA during that time period. Dr. Thapar provided two lists of late reports and the reasons for being late **(Exhibits 33, 34)**. During my review of 15-day reports, I also noted reports that were submitted late that were not on the list. Examples include:

[redacted]

- Case 2008AL001710, Digoxin Tablets, received on 2/7/2008 and submitted to FDA on 3/31/2008 **(Exhibit 36)**.

[redacted]

Due to limitations of the firm's database, Oracle AERS, the firm was unable to generate line listings of late reports. According to Dr. Thapar, the firm tracks late reporting by performing a manual monthly reconciliation of reports submitted to FDA; however, their manual system for tracking late reporting does not capture all reports submitted beyond the 15-days. For example, if the firm was conducting a monthly reconciliation of reports submitted to FDA for the month of March 2008, they would target only reports with a "Date received by manufacturer" of March 2008 on the Medwatch form. If a report was sent to the firm late (in March) from a foreign affiliate with a received date of 2/1/2008, this report would not be picked up as a late report during the reconciliation. In discussions with Dr. Thapar and Mr. Delicato regarding this issue, Dr. Thapar stated they will look into purchasing a software program for the AERS database, if available, to allow them to conduct searches and manage late reporting.

OBSERVATION 3

[redacted]

Discussion with Management:

Dr. Thapar provided periodic reports that were submitted to FDA beyond the established timeframe. For the past two years, there were two quarterly reports submitted late due to the firm's regulatory Affairs department did not notify the Medical Affairs department of approval of the two products [redacted]

Digoxin Tablets, [redacted] did not observe any deficiencies or additional reports submitted late to FDA.

Production System

OBSERVATION 4

The flow of in-process materials though the building is not designed to prevent contamination.

[redacted]

Reference: 21 CFR 211.42(b)

Discussion with Management:

During my walkthrough of the manufacturing area, I observed in room MFG PR-12 a rack of uncovered trays containing an in-process material. Mr. Delicato explained to me that the material was granulation for [redacted] and that unlike other granulations that are dried in the oven, this granulation is dried at room temperature. The product was granulated in room MFG PR-6, which the granulation is placed on trays and then transported to room MFG PR-12 to dry. I asked if the trays were covered when brought into the room for drying. Mr. Delicato stated that the trays were uncovered when brought into the room. I discussed my concern regarding the uncovered trays containing the granulation and the practice of transporting the material in a common corridor where the manufacturing suites are located. Mr. Delicato acknowledged my concern. A manufacturing batch record and room clearance forms for Diclofenac Sodium ER Tablets are provided as **Exhibits 42 and 43** as an example of a batch that was granulated and dried in different rooms. During the inspection, Mr. Delicato stated that the practice of transporting the granulation in uncovered trays has been discontinued and provided an updated batch record that indicated that the trays need to be covered during transport **(Exhibit 44)**.

REFUSALS

I did not encounter any refusals during the inspection.

GENERAL DISCUSSION WITH MANAGEMENT

I discussed the following item with the firm's management during the inspection:

- **Not all employees received training in postmarketing adverse drug experiences**

In discussion with Dr. Thapar and Mr. Delicato concerning training, they informed me that employees within Quality Assurance, Medical Affairs, Legal, Customer Service and the receptionists receive postmarketing adverse drug experience training; however, departments such as Manufacturing and Regulatory Affairs do not receive the training. I stated that all employees should receive some level of training for adverse drug experiences in case they ever receive information that may meet the criteria for an adverse drug experience concerning any of the company's drug products. Dr. Thapar and Mr. Delicato stated that they understood my concern and indicated that they were going to add the ADE training for all employees.

VOLUNTARY CORRECTIONS

During the inspection, I reviewed corrective actions from the previous GMP inspection of 12/13/2006 to 1/29/2007 and from the postmarketing adverse drug experience (PADE) inspection at the firm's Actavis Totowa LLC, Little Falls, New Jersey location from 1/10/2006 to 2/8/2006.

With regard to the previous GMP inspection, deficiency was noted concerning laboratory out-of-specifications results, which were not thoroughly investigated and were inconclusively attributed to analyst error. During the current inspection, I reviewed several laboratory investigations and did not observe similar deficiencies.

Regarding the PADE inspection at the Actavis Totowa LLC, Little Falls, New Jersey location, deficiencies noted during the inspection included the following:

- Potential 15-day cases were not submitted to FDA
- Serious and unexpected ADE reports were not promptly or adequately investigated
- Cases were not reviewed for seriousness and expectedness; submitted cases were classified as a 15-day report
- Periodic safety reports have never been submitted to FDA
- Written procedures have not been established for follow-up investigations, adequate completion of MedWatch forms, maintenance of records to assure timely submission of 15-day reports and evaluation of adverse event data for serious outcome and event expectedness.

In 8/2006, FDA sent a warning letter to the firm as a result of the PADE inspection. The firm's corrective actions to the warning letter included transferring reporting responsibilities for products manufactured in Little Falls, New Jersey to Actavis Elizabeth since the firm had established procedures and personnel. According to Sarita Thapar, Pharm.D., Director, US Medical Affairs, the products were merged into their operations and did not require additional procedures. In review of the issues cited in the warning letter, I observed a similar deficiency during the current inspection. This deficiency concerned serious and unlabeled cases meeting the criteria for a 15-day report were not submitted to FDA **(refer to FDA 483 Observation 1).**

Establishment Inspection Report	FEI:	2211563
Actavis Elizabeth LLC	EI Start:	04/21/2008
Elizabeth, NJ 07202-1106	EI End:	05/21/2008

SAMPLES COLLECTED

I did not collect any samples during the inspection.

[redacted]

[redacted]

36. Case 2008AL001710, Digoxin Tablets (2pp)

[redacted]

ATTACHMENTS

- CDER Hardcopy assignment, (22pp)
- Form FDA 482, Notice of Inspection, dated 4/21/2008 (1p)
- Form FDA 482, Notice of Inspection, dated 5/19/2008 (1p)
- Form FDA 483, Inspectional Observations, dated 5/21/2008 (3pp)

Douglas C. Kovacs, Investigator